



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,045	12/18/2000	Jacques Bauer	GEI-084	6820

20311 7590 12/15/2003

MUSERLIAN AND LUCAS AND MERCANTI, LLP
475 PARK AVENUE SOUTH
NEW YORK, NY 10016

EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.

09/720,045

Applicant(s)

BAUER ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2001 and 28 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8 and 16-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8 and 16-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The Sequence Listing filed March 28, 2003 was not accompanied by a statement that the sequence listing includes no new matter. See 37 CFR 1.821(g).

Correction is required.

The Sequence Listing filed March 28, 2003 was approved by STIC for matters of form.

2. The abstract of the disclosure is objected to because it is insufficiently detailed as to the specific pharmacological uses of the claimed compounds. The abstract should also be in the form of a single paragraph. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: There is no Brief Description of the Drawings as required by 37 CFR 1.74. Appropriate correction is required.

4. The drawings are objected to because in the heading to Figure 5, "effect" is misspelled, and in Figure 10, the text of the heading is repeated. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. Two preliminary amendments were filed in this application, each containing a new claim 20. In the preliminary amendment filed December 18, 2000, the claim which is numbered "20" ("A method of modulating immune responses...") will retain its claim number. In the preliminary amendment filed February 27, 2001, the new claims which were numbered "20" through "30" have been re-numbered as "21" through "31", respectively, under 37 CFR 1.126.

Art Unit: 1654

Any future reference to these claims will use their re-numbered claim numbers. In the response to this Office action, Applicants are required to re-number these claims in the Amendment section of their response consistent with the above renumbering, and are required to correct the dependencies of claims 4-8 and 22-31 consistent with the above renumbering.

6. Claims 4-8 and 16-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4-8 refer to “the compound of claim [21]”. However, claim 21 is drawn to a N-acyl-dipeptide and nowhere uses the term “compound”. Claim terminology needs to be standardized in order to avoid issues concerning antecedent basis. Claims 22-26 and 31 raise the same issues with respect to antecedent basis and claim terminology. Claim 4 is indefinite because the “and/or” language is improper Markush language. Further, possibly because of formatting, it is unclear what relationship the various substituents and numbers, especially the “10-diol”, the “1”, and the “10-dihydrogenphosphate”, have with each other. Claims 16 and 20 are dependent upon canceled claim 1. Claim 21, line 13, uses the variable n_1 in the structural formula, but defines the variable n' . Claim terminology needs to be standardized. At claim 21, line 16, “and” should be inserted after “sulfonyl,” so that standard Markush terminology is used. Claim 25, lines 1-9, recites process steps by which a compound of the formula recited at line 10 is to be obtained. However, none of the groups present in the reactants of lines 1-9, especially the $(CH_2)_p$, the $(CH_2)_{q+1}$, and the R_2 groups, are present in the compound of line 10. It is believed that the wrong formula has been inserted at line 10. Claim 25 is indefinite because it requires reaction “with a ω -hydroxy, amino or thioamino acid of Formula III”; however, Formula III is not recited or defined in the claim.

Art Unit: 1654

Claim 26, formulas (III) and (IV), are incorrect because each has an internal carbon atom which shows only two filled valences. It is not clear what is attached to the other two valences. In claim 26, the reaction of compounds of formulas (II) and (III) to form the compound of formula (IV) appears to be incorrect, because the compound of formula (IV) shows the presence of $(RO)_2-P$ and R_1 groups which are not present in any of the claimed reactants used to produce the compound of formula (IV). Claim 26 is indefinite because the variable "R" used in formula (IV) is not defined in the claim. Claims 29 and 30 refer to "The method of claim 25"; however, claim 25 is drawn to a process, not a method. Claim terminology needs to be standardized.

7. Claims 4, 6, 21, 22, and 24-31 are objected to because of the following informalities: The preliminary amendment to claim 4 filed February 27, 2001 deleted the beginning parenthesis from line 1. Accordingly, the end parenthesis after "dodecanoyloxytetradecanoylamino" in line 2 is unmatched. At claim 6, line 2, "dodecanoyloxytetradecanoylamino" is misspelled. At claim 21, line 6, "alkyl" is misspelled. At claim 21, page 2 of the preliminary amendment, line 7, "phosphono" is misspelled. At claim 26, line 2, a verb, probably "blocking", is missing from after "comprising". At claim 26, line 5, "the latter" appears to refer to the blocking agent rather than to the COOH group of the formula at line 4. Analogously, the phrase "the latter" at line 8 does not appear to refer to the correct compound. At claim 26, line 6, "COOH" is misspelled. Applicants' use of the $q+1$ and q subscripts in claim 26 appears to be incorrect. In the formula at line 4, there are $q+1$ CH_2 groups. When this is combined with the CH_2 group which results from reducing the free COOH group, there will be $q+2$, not q , CH_2 groups. It is possible that Applicants intended " $q-1$ " rather than " $q+1$ ". This subscript should also be checked in claim 25. At claim 26, fifth-to-last line, "agent" is misspelled. At claim 29, line 2, "tetradecanoic" is

Art Unit: 1654

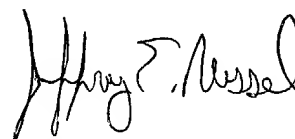
misspelled. At claim 30, line 2, "hydroxytetradecanoic" is misspelled. Appropriate correction is required.

8. Claims 4-8 and 16-31 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the claim objections set forth in this Office action. The prior art of record does not teach or suggest compounds having the structures recited in instant claims 16 and 21. Accordingly, methods of making, methods of using, and pharmaceutical compositions comprising the compounds are also novel and unobvious over the prior art of record.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

PLEASE NOTE: Sometime on or around January 6, 2004, the examiner will be moving to the new USPTO headquarters. At that time, the examiner's phone number will change to (571) 272-0969. After January 6, it is recommended that Applicants attempt to contact the examiner at the new phone number if they are unable to reach him using the old number.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
December 10, 2003